

APR 11 2006

Exhibit 1

Mega Motion, Inc.

Products for Better Living

K 060697

Travel Pal 510(k) Summary

Submitter's Name & Address:

Mega Motion, Inc.
957 Wood Street
Old Forge, Pa. 18518
Phone: (888) 415-1200
Facsimile: (888) 415-1210

Contact Person:

Mark Calomino
Official Correspondent

Date Prepared:

03-02-06

Name of Device and Proprietary Name:

Travel Pal (MM-111B) /
Mega Motion

Common or Usual Name:

3-Wheel Power Scooter

Classification Name:

Vehicle, Motorized 3-
Wheeled

Product Code:

INI

Device Description:

The Travel Pal is a compact battery-operated Three Wheel power Scooter featuring rear anti-tip wheels, a standard digital controller, and a foldable tiller. The Travel Pal is designed for, but not limited to Mega Motion, Inc. providers / retailers and their consumers.

As a motorized Scooter, the Travel Pal offers economical mobility, and is equipped with; electronic regenerative disc brakes, off-board battery charger, and removable batteries. Accessories include a front basket.

The Travel Pal is designed with ultimate safety, stability, performance, and portability in mind. The product also has a lightweight, foldable seat, which is removable and allows for ease of portability when traveling or storing the unit.

Comparison to Predicate Devices:

The Travel Pal is substantially equivalent to Mega Motion, Inc. Mega3, MM-333 (K982145) when comparing configuration, maneuverability, stability, and structure. The performance characteristics and the position of the drive mechanisms are similar to achieve the same intended use function that enables

Mega Motion, Inc.

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the user to maintain optimum stability without hindering performance. Both utilize rear drive and rear anti-tip wheels. The key functional change between the Mega3 and the Travel Pal is the Travel Pal's frame is one piece, and batteries are accessible by shroud removal.

Intended Use:

The intended use of the Mega Motion, Inc, Travel Pal Powered Scooter is to provide mobility to persons that have limited walking capabilities or simply those who wish to ride a scooter for transportation purposes.

Non-Clinical Testing:

Compliance to applicable Testing Standards is as follows:

ANSI/RESNA WC/93 Maximum Overall Dimensions

ANSI/RESNA WC/01 Determination of Static Stability

ANSI/RESNA WC/02 Determination of Dynamic Stability

ANSI/RESNA WC/03 Effectiveness of Brakes

ANSI/RESNA WC/04 Determination of Energy Consumption – Theoretical Range

ANSI/RESNA WC/05 Overall Dimensions, Mass & Turning Space

ANSI/RESNA WC/08 Test methods for Static, Impact and Fatigue Strengths

ANSI/RESNA WC/09 Climatic Tests

ANSI/RESNA WC/10 Obstacle Climbing

ANSI/RESNA WC/15 Documentation and Labeling

ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.

CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The Travel Pal has the same intended use and similar technological characteristics as the Mega3 MM333 (K982145), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Travel Pal is substantially equivalent to the predicate device (Mega 3 MM333). The Travel Pal has passed all the necessary testing procedures and is considered to be safe for user operation.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2006

Mega Motion, Inc.
c/o Mr. Mark Calomino
957 Wood Street
Old Forge, Pennsylvania 18518

Re: K060697
Trade/Device Name: Travel Pal – 3 Wheel Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: March 6, 2006
Received: March 16, 2006

Dear Mr. Calomino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

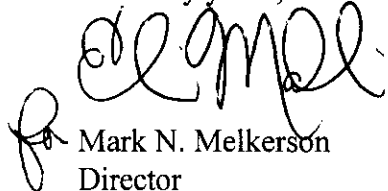
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Melkerson", with a stylized initial "M" and "N".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Travel Pal – 3 Wheel Scooter

Indications for Use:

The intended use of the Mega Motion Inc., Travel Pal Powered Scooter, is to provide mobility to persons that have limited walking capabilities or simply those who wish to ride a scooter for transportation purposes.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060697